

REMARKS/ARGUMENTS

Claims 2, 5, 6, and 8-38 were pending in the subject application. Applicants have herein canceled claim 13 without prejudice. Applicants respectfully note that claim 2 has been amended to include the subject matter of claim 13 and claim 5 has been amended to correct a typographical error. Applicants have also added claims 53 and 54. This amendment does not involve any issue of new matter. Support for these amendments may be found *inter alia* in the specification as follows: Claim 53, page 3, lines 22-24; and Claim 54, page 6, lines 26-35. Applicants respectfully request entry of the subject amendment such that claims 2, 5-6, and 8-12, 14-38, 53 and 54 will be pending.

Rejection Under 35 U.S.C. '103

The Examiner rejected claims 2, 5, 6, 8-20, 24, 27, 35-38 under 35 U.S.C. §103 as being allegedly unpatentable over Kubersampath (AH) in view of Anderson. The Examiner alleges that there is a tendency to use dialysis therapy early in acute renal failure, that kidney malfunction causes a calcium and phosphate imbalance in the blood, that such an imbalance leads to bone fractures and other effects including loss of bone mass, and that the cited references teach that OP-1 may be administered to a mammal to treat loss of bone mass. The Examiner concludes that “it would have been obvious to one of ordinary skill in the art at the time of Applicant’s invention to administer OP-1 to a mammal afflicted with acute renal failure, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification in order to prevent loss of bone mass and/or increase bone mass in the mammal with kidney disease or renal malfunction” (emphasis added).

In response, applicants respectfully traverse the Examiner’s above rejection. Applicants point out that claim 2 relates to a method of delaying the need, or reducing the frequency of, dialysis treatment, and not to a method of increasing bone mass. The Examiner’s arguments do not apply to claim 2 because they do not support an expectation of success that treatment with a morphogen will reduce the frequency of dialysis treatment in a subject afflicted with acute renal failure. Even if a subset of subjects receiving morphogens to prevent bone loss were concurrently undergoing dialysis for treatment of acute renal failure as the Examiner alleges, there is no teaching, motivation or suggestion in the references cited that the morphogen will

delay or reduce the need for dialysis treatment or that it will improve renal function. The Examiner's reasoning assumes that reducing bone loss with a morphogen results in reduced dialysis treatment, where no such cause and effect relationship has been presented by the Examiner.

Applicants contend that the administration of a compound to treat a first disorder in a subject does not make obvious the use of the same compound for the treatment of a second disorder, even if a subset of the patients afflicted with the first disorder are also afflicted with the second disorder. This is particularly relevant in cases, such as the present case, where the first and second disorders have substantially distinct pathologies i.e. loss of bone mass vs. loss of renal function. According to the Examiner's reasoning, any compound or composition which is used to treat bone loss can also be used to reduce or delay the need for dialysis in subjects afflicted with acute renal failure with an expectation of success. Thus, the Examiner would also conclude that calcium, vitamin D or estrogen supplements (in women) may be used to reduce the frequency or need for dialysis treatment with a reasonable expectation of success, since these compounds are used to treat bone loss, and thus claims to the use of such compounds for the treatment of a renal condition would be obvious. (Harrison's Principles of Internal Medicine, 15th Edition, McGraw Hill Co., 2001, pp. 2229). Based on these arguments, Applicants contend that the Examiner has not presented a case of obviousness.

Applicants further refer the Examiner to 35 U.S.C. 100b, which recites "The term "process" means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material" (emphasis added). Furthermore, 35 U.S.C. 100b recites "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof..." Applicants have discovered a new use (delaying the need for, or reducing the frequency of, dialysis treatment) of a known composition i.e. morphogens, and therefore the claimed invention constitutes patentable subject matter.

To further clarify the invention, Applicants have added claim 53. Support for the amendment may be found, inter alia, in originally filed claims 1, 7, and 13 and on page 3, lines 22-24 of the specification. Claim 53 recites a method of delaying, preventing, inhibiting, or alleviating

permanent or progressive loss of renal function in a mammal afflicted with acute renal failure. The subject matter is patentably distinct over the cited references because the cited references in combination fail to provide a teaching, a suggestion, or an expectation that treatment with a morphogen of a subject afflicted with acute renal failure will improve kidney function. The cited references teach the use of morphogens for increasing bone mass, but are silent as to the effects of a morphogen in the physiological function of the kidney, or as to the effects of bone morphogens on markers of renal function in patients afflicted with acute renal failure. As presented earlier, the use of morphogens to treat one condition, bone loss, does not make obvious the use of morphogens to treat a second condition, loss of renal function, especially when the pathology of the two conditions is substantially different. Accordingly, applicants respectfully request allowance of claim 53 and its dependent claims.

The Examiner also rejected claims 2, 23 and 24 under 35 U.S.C. §103 as being allegedly unpatentable over Kubersampath (AH) in view of Anderson as applied to claim 2, and further in view of Spragg, Saavedra and Kubersampath (AG). The Examiner argues that claim 2 is obvious based on Kuberasampath (AH) and Anderson. The Examiner then uses references Spragg, Saavedra and Kubersampath (AG) to support the alleged case of obviousness for claims 23 and 24, which are dependent on claim 2.

Applicants respectfully traverse the Examiner's rejection. Applicants have shown in the sections above that Kuberasampath (AH) and Anderson do not form the basis for a *prima facie* case of obviousness with respect to claim 2. Furthermore, Spragg, Saavedra and Kubersampath (AG) fail to provide a teaching, suggestion, motivation, or expectation of success on their own, or when combined with Kuberasampath (AH) and Anderson, for improving renal function in a subject afflicted with acute renal failure by administration of a morphogen. Accordingly, since claims 2 is not obvious over the cited prior art, and claims 23 and 23 directly depend on claim 2, claims 23 and 24 are not obvious.

Rejection under 35 U.S.C. 112, first paragraph

The Examiner rejected claims 2, 8-20, 23, 24, 27, 35-38, 7-20, 23, 24, 27 and 35-38 as allegedly not enabled, stating that the specification does not reasonably provide enablement for a method of treatment comprising administering the other OP/BMP renal therapeutic agents recited in the

claims. The Examiner suggests amending claim 2 to include functional language for the BMP agent, and states that claim 13 is the only claim reciting a functional limitation. In response, Applicants, without conceding the correctness of the Examiner's position, have amended claim 2 to include the functional language of claim 13, and have canceled claim 13 without prejudice. Accordingly, Applicants respectfully request that this ground of rejection be removed.

Claim Objections

The Examiner objected to the term "BMPS" in claim 5 and suggests substitution with the term "BMP5". Applicants have amended claim 5 to as requested by the Examiner. Accordingly, Applicants respectfully request that this ground of objection be removed.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

No fee is deemed necessary in connection with this amendment. However, if any fee is necessary, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 18-1945, under order No. JJJ-P01-514.

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